DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

University of Texas Medical School at Houston
% K. Lance Gould, M.D.
Professor of Cardiovascular Medicine
6431 Fannin Street, Suite MSB 4.256
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April 14, 2015

Re: K143664
Trade/Device Name: HeartSee
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: December 22, 2014
Received: January 15, 2015

Dear Dr. Gould:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See *PRA Statement below.*

510(k) Number *(if known)*
K143664

Device Name
HeartSee

Indications for Use *(Describe)*

The cardiac positron emission tomography (PET) analysis tool, HeartSee is a software package intended for use by nuclear medicine and nuclear cardiology physicians and technologists to facilitate image interpretation. Archiving of output data will be supported for clinical diagnostics, quality control, and research.

HeartSee contain two fundamental components. First, the software can import cardiac PET images in DICOM format from any PET camera from any camera manufacturer. These images can be reoriented to cardiac axes to produce standard tomographic and topographic displays of relative uptake. A trained, licensed physician can interpret these processed images as per standard practice.

Second, the CFR software can quantify absolute myocardial blood flow per unit tissue (cc/min/gm) in stress and rest PET cardiac images and quantitatively assess the coronary flow reserve (CFR).

Type of Use *(Select one or both, as applicable)*

X Prescription Use (Part 21 CFR 801 Subpart D)

D Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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5. 510(k) Summary

Owner/Contact:

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Date of preparation: December 22, 2014

Device trade name: HeartSee

Common name: Cardiac Positron Emission Tomography (PET) Analysis Software

Classification names: emission computed tomography system (21 CFR 892.1200, Product Code KPS)

Devices claimed for equivalence:

- K090178, NeuSoft Positron Attrius scanner (CARDIAC software component)
- K113754, cfrQuant

General description: The cardiac positron emission tomography (PET) analysis tool HeartSee is a software package intended for use by nuclear medicine and nuclear cardiology physicians and technologists to facilitate image interpretation. Archiving of output data will be supported for clinical diagnostics, quality control, and research.

HeartSee contains two fundamental components. First, the software can import cardiac PET images in DICOM format from any camera manufacturer. These images can be reoriented to cardiac axes to produce standard tomographic and topographic displays of relative uptake. A trained, licensed physician can interpret these processed images as per standard practice.

Second, the CFR software can quantify absolute myocardial blood flow per unit tissue (cc/min/gm) in stress and rest PET cardiac images and quantitatively assess the coronary flow reserve (CFR).

To compute coronary flow reserve (CFR) – the ratio of increased blood flow (stress) to baseline blood flow (rest) – three inputs are required: integrated arterial activity in the early part after bolus injection, average myocardial activity

in the late part after bolus injection, and correction factors for partial volume effects of the PET scanner. The first number comes from a region of interest (ROI) drawn in the thoracic aorta or left atrium on images taken soon after radionuclide bolus administration. The second number comes from the topographic maps of myocardial uptake acquired later after radiotracer injection. The third number varies by PET camera and will be initialized in a user preference file.

Intended use: HeartSee is intended for processing of DICOM images, visual analysis and quantification of relative myocardial tracer uptake, and quantification of absolute myocardial blood flow and CFR when applied to diagnostic cardiac PET images in patients with suspected or known coronary artery disease.

Technological characteristics: HeartSee is a software package that uses standard, industrial computing hardware and applications.